STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

June 27, 2019

Ms. Donna Hadley, CEO
William W Backus Hospital
326 Washington St
Norwich, CT 06360

Dear Ms. HadleyPatel:

An unannounced visit was made to William W Backus Hospital on May 1 and 2, 2019 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations and a certification survey.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by July 7, 2019.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by **July 7, 2019** or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

An office conference has been scheduled for **August 1, 2019** at **10:00 AM** in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to

DATES OF VISIT: May 1 and 2, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

retain legal representation, your attorney may accompany you to this meeting.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Suisan Newton, R.N., B.S.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SN/PB:jf

Complaints #25290, #24757 and #24754

DATES OF VISIT: May 1 and 2, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Adinistration (2) and/or (i) General (6)

1. Based on a review of facility documentation, interviews with staff, and policy review, the Governing Body failed to have a system in place to monitor the contracted service for Food and Dietetic Services to ensure that appropriate actions were taken and documented when kitchen refrigerator temperatures were out of range and/or failed to have a mechanism in place to ensure that food remained safe to consume when refrigerator temperatures were out of range. The findings include the following:
    a. The hospital's dietary department utilized a Temp Trak system to monitor the temperatures for all refrigerators and freezers 24 hours a day. Review of the Temp Trak system data identified multiple occasions when the refrigerator temperatures were not within the acceptable range of 32-45 degrees Fahrenheit (°F).
        i. Review of the Temp Trak system during the period of 4/12/19 and 4/16/19 identified that temperatures were not within the acceptable range for one or more refrigerators on 31 occasions, as indicated by the system's recently cleared (acknowledged) alert conditions.

        On 28 of the 31 occasions (between 4/12/19 and 4/16/19), documentation failed to identify that staff identified the cause and/or provided remediation.

        Review of maintenance work orders between 4/4/19 and 4/16/19 indicated that a work order dated 4/15/19 noted ice was forming on the fan in the dairy walk-in refrigerator. There was no documentation that identified the cause and/or remediation for 30 of the 31 alerts.

        Interview with IT #1 on 5/1/19 at 11:00 AM identified that the Temp Trak system would alarm if the temperature did not meet the identified parameters (32-45°F) for one hour, and would reset automatically once the identified parameters are met for one hour. IT #1 stated that there were times when the Temp Trak system alarmed and it could be hours to days later when the alarm was acknowledged or cleared. For example, on 4/12/19 at 2:00 PM the cold prep refrigerator (vegetables/condiments) alarmed for a temperature of 47.5°F. The Temp Trak log indicated that the alarm reset itself at 5:00 PM (3 hours later), however the alarm was not acknowledged or cleared until 4/13/19 at 3:18 PM (25 hours later).

        Interview with Dietary Worker (DW) #1 on 5/1/19 at 1:30 PM indicated that she checks the alarm notifications on her arrival at 5:30 AM, at 11:30 AM, 1:30 PM and the evening shift staff check prior to leaving at 7:30 PM. DW #1 indicated that if the temperatures are high (50°F or higher) she reports this to a supervisor, however, was unable to provide associated documentation for the out of range readings. DW #1 further stated that when the alarm codes are reviewed she clears them and from a prepopulated list chooses the statement "monitoring status" which means she will continue to monitor. DW #1 further indicated that prior to the Dietary Supervisor

leaving about a month ago, she used to keep her computer on at all times so if a temperature alarmed staff would know in real time while the department was open (5:00 AM -8:00 PM) and could check the alarm. However, since her departure there was no "real time" system in place. DW #1 stated she uses the computer for other tasks and cannot leave it on the temperature tracking system. In addition, there is no monitoring of the alarm system when the dietary department is closed.

Interview with the Dietary Director on 5/1/19 at 9:15 AM identified that the Temp Trak system is manually monitored 3 times a day. If there is a system alert staff are expected to check the temperature, clear the alert and notify maintenance staff or the supervisor of any issues.

Interview with the Executive Chef on 5/1/19 at 9:30 AM indicated that four times a day the Temp Trak system is checked by dietary office staff and if there is an alert, staff should manually check the temperature, clear the alert, and fill out a work order if there is an issue.

Review of the policy for Refrigerator/ Freezer Temperature Monitoring Maintenance indicated that food refrigeration will be between 36-40°F.

ii. Review of Temp Trak reports between 4/11/19 and 4/17/19 indicated that the sensor #222-248 (cook prep refrigerator) registered temperatures of 68 to 70°F. Review of maintenance logs and interview with the Dietary Director and the Executive Chef on 5/1/19 at 1:50 PM stated this refrigerator had been taken out of service on 2/28/19 and replaced with a new refrigerator. The Director of Dietary indicated that a Temp Trak sensor had not been placed on the new cook prep refrigerator and that refrigerator temperatures had not been monitored from 2/28/19 to 4/16/19.

iii. "Recently Cleared Alert Conditions" documentation was reviewed with the Information Technologist (IT) responsible for the Temp Trak system on 5/1/19 at 11:00 AM. Between 4/12/19 and 4/16/19, sensor 76-137E alarmed and was cleared 11 times. Review of the facility documentation indicated that the alarm was being triggered due to high temperatures and a low battery in the sensor. The documentation failed to reflect that the low battery issue was addressed.

Interview with the Regional Director of Quality on 5/2/19 at 11:50 AM identified that the contracted service of food and dietetics is reviewed annually by the Medical Executive Committee. The System Director of Food and Nutrition meetings dated 2/1/19 and 4/5/19 identified agenda items of financial review, patient experience and operations update. The issue of kitchen refrigerator temperatures being out of range over time was not addressed.

The hospital discontinued the use of the Temp Trak system on 4/16/19. Facility staff began obtaining refrigerator and freezer temperatures every four hours as well as monitoring food temperatures. Repairs were made to refrigerators and freezers and staff

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throughout the dietary department were reeducated on food safety practices.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Adinistration (2) and/or (h) Dietary Service (1)

2. Based on a review of facility documentation, interviews and policy review, the facilty failed to ensure that a comprehensive QAPI program was established for the Food and Dietetics Services department to monitor the effectiveness and safety of services with monitoring and/or responding to refrigerator temperatures that were out of range to ensure that food remained safe to consume. The findings include the following:
    a. Review of the hospital's Local Health Department report dated 8/22/18 indicated that the hospital's walk-in cooler temperatures were above the 41 degree Fahrenheit (°F) threshold, with deli meat being 43°F. The report indicated that the items were discarded. A Local Health Department survey was conducted on 3/8/19 that identified the facility failed to ensure that cold storage met the identified parameters (below 41°F), and that the items were voluntarily discarded. A Local Health Department survey was conducted on 3/22/19 and indicated that the facility failed to ensure that cold storage met the identified parameters (below 41°F), and that numerous items were voluntarily discarded. The report indicated that a meeting with the local health department and the facilty would be scheduled due to repeated critical violations. A Local Health Department survey was conducted on 4/16/19 that identified that the facility failed to ensure that cold storage met the identified parameters (below 41°F), requiring items to be discarded.

        Review of the Food and Nutrition quality assurance (QA) data for 2016, 2017 and 2018 indicated that the indicators reviewed were three categories from the Press Ganey patient evaluation. The items reviewed were the quality of food, temperature of food, and courtesy of the server. Although the department had ongoing issues with maintaining appropriate food temperatures, the department's QA focused on the outcome of meals, not on the storage and preparation of the food.
    b. The hospital's dietary department utilized a Temp Trak system to monitor the temperatures for all refrigerators and freezers 24 hours a day. Review of the Temp Trak system data during the period of 4/11/19-4/17/19 identified multiple occasions when the refrigerator temperatures were not within the acceptable range of 32-45°F. Facility documentation failed to indicate steps taken to remediate the issue.

        Interview with IT #1 on 5/1/19 at 11:00 AM indicated that there were times when the Temp Trak system alarmed and it could be hours to days later when the alarm was acknowledged or cleared. For example, on 4/12/19 at 2:00 PM the cold prep refrigerator (vegetables/condiments) alarmed for a temperature of 47.5°F. The Temp Trak log indicated that the alarm reset itself at 5:00 PM (3 hours later), however the alarm was not acknowledged or cleared until 4/13/19 at 3:18 PM (25 hours later).

        Interview with the Executive Chef on 5/1/19 at 9:30 AM indicated that three times a day the Temp Trak system is checked by dietary office staff and if there is an alert, staff are supposed to manually check the temperature, clear the alert, and fill out a work order if

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there is an issue.

Interview with Dietary Worker (DW) #1 on 5/1/19 at 1:30 PM indicated that she checks the alarm notifications on her arrival at 5:30 AM, at 11:30 AM, 1:30 PM and the evening shift staff check prior to leaving at 7:30 PM. DW #1 indicated that if the temperatures are high (50 degrees or higher) she reports this to a supervisor, however there is no associated documentation. DW #1 indicated that when the alarm codes are reviewed she clears them and from a prepopulated list chooses the statement "monitoring status" which means she will continue to monitor. DW #1 indicated that prior to the Dietary Supervisor leaving about a month ago she used to keep her computer on at all times so if a temperature alarmed staff would know in real time while the department was open (5:00 AM -8:00 PM) and could check the alarm. However, since her departure there is no real time system in place. DW #1 indicated that she uses the computer for other tasks and cannot leave it on the temperature tracking system. In addition, there is no monitoring of the alarm system when the dietary department is closed.

Interview with the Regional Director of Quality on 5/2/19 at 11:50 AM identified that the contracted service of food and dietetics is not incorporated in the hospital's quality improvement council.

The facility failed to have an effective QAPI program for the Food and Dietetics Services department to ensure that food remained safe to consume when refrigerator temperatures were out of range.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (h) Dietary Service (i) and/or (i) General (6)

3. *Based on a review of facility documentation, interviews with staff, and policy review, the Director of Food and Dietetic Services failed to effectively supervise the day to day operations of the dietary department including failure to respond to out of range refrigerator temperatures to ensure the safety of patients, staff, and the general public. The findings include the following:
    a. The hospital's dietary department utilized a Temp Trak system to monitor the temperatures for all refrigerators and freezers 24 hours a day. Review of the Temp Trak system data identified multiple occasions when the refrigerator temperatures were not within the acceptable range of 32-45 degrees Fahrenheit (°F).
        i. Review of the Temp Trak system during the period of 4/12/19 and 4/16/19 identified that temperatures were not within the acceptable range for one or more refrigerators on 31 occasions, as indicated by the system's recently cleared (acknowledged) alert conditions.

            On 28 of the 31 occasions (between 4/12/19 and 4/16/19), documentation failed to identify that staff identified the cause and/or provided remediation.

            Review of maintenance work orders between 4/4/19 and 4/16/19 indicated that a work order dated 4/15/19 noted ice was forming on the fan in the dairy walk-in refrigerator.

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There was no documentation that identified the cause and/or remediation for 30 of the 31 alerts.

Interview with IT #1 on 5/1/19 at 11:00 AM identified that the Temp Trak system would alarm if the temperature did not meet the identified parameters (32-45°F) for one hour, and would reset automatically once the identified parameters are met for one hour. IT #1 stated that there were times when the Temp Trak system alarmed and it could be hours to days later when the alarm was acknowledged or cleared. For example, on 4/12/19 at 2:00 PM the cold prep refrigerator (vegetables/condiments) alarmed for a temperature of 47.5°F. The Temp Trak log indicated that the alarm reset itself at 5:00 PM (3 hours later), however the alarm was not acknowledged or cleared until 4/13/19 at 3:18 PM (25 hours later).

Interview with Dietary Worker (DW) #1 on 5/1/19 at 1:30 PM indicated that she checks the alarm notifications on her arrival at 5:30 AM, at 11:30 AM, 1:30 PM and the evening shift staff check prior to leaving at 7:30 PM. DW #1 indicated that if the temperatures are high (50°F or higher) she reports this to a supervisor, however, was unable to provide associated documentation for the out of range readings. DW #1 further stated that when the alarm codes are reviewed she clears them and from a prepopulated list chooses the statement "monitoring status" which means she will continue to monitor. DW #1 further indicated that prior to the Dietary Supervisor leaving about a month ago, she used to keep her computer on at all times so if a temperature alarmed staff would know in real time while the department was open (5:00 AM -8:00 PM) and could check the alarm. However, since her departure there was no "real time" system in place. DW #1 stated she uses the computer for other tasks and cannot leave it on the temperature tracking system. In addition, there is no monitoring of the alarm system when the dietary department is closed.

Interview with the Dietary Director on 5/1/19 at 9:15 AM identified that the Temp Trak system is manually monitored 3 times a day. If there is a system alert staff are expected to check the temperature, clear the alert and notify maintenance staff or the supervisor of any issues.

Interview with the Executive Chef on 5/1/19 at 9:30 AM indicated that four times a day the Temp Trak system is checked by dietary office staff and if there is an alert, staff should manually check the temperature, clear the alert, and fill out a work order if there is an issue.

Review of the policy for Refrigerator/ Freezer Temperature Monitoring Maintenance indicated that food refrigeration will be between 36-40°F.

The facility failed to ensure the mechanism in place was effective and/or that the Director adequately supervised the day to day operations to address the out of range temperatures which had the potential to affect food safety.

ii. Review of Temp Trak reports between 4/11/19 and 4/17/19 indicated that the sensor

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#222-248 (cook prep refrigerator) registered temperatures of 68 to 70°F. Review of maintenance logs and interview with the Dietary Director and the Executive Chef on 5/1/19 at 1:50 PM stated this refrigerator had been taken out of service on 2/28/19 and replaced with a new refrigerator. The Director of Dietary indicated that a Temp Trak sensor had not been placed on the new cook prep refrigerator and that refrigerator temperatures had not been monitored from 2/28/19 to 4/16/19.

iii. "Recently Cleared Alert Conditions" documentation was reviewed with the Information Technologist (IT) responsible for the Temp Trak system on 5/1/19 at 11:00 AM. Between 4/12/19 and 4/16/19, sensor 76-137E alarmed and was cleared 11 times. Review of the facility documentation indicated that the alarm was being triggered due to high temperatures and a low battery in the sensor. The documentation failed to reflect that the low battery issue was addressed.

The hospital discontinued the use of the Temp Trak system on 4/16/19. Facility staff began obtaining refrigerator and freezer temperatures every four hours as well as monitoring food temperatures. Repairs were made to refrigerators and freezers and staff throughout the dietary department were reeducated on food safety practices.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2)(3) and/or (c) Medical Staff (2)(B) and/or (d) Medical Records (3), and/or (i) General (6),

4. *Based on clinical record review, interview and policy review for one of three patients (Patient #2) the facility failed to ensure that the rationale for the administration of an anti-psychotic was documented. The findings include the following:
    a. Patient #2 presented to the emergency department on 10/21/18 at 4:57 PM with shortness of breath. The patient had a past medical history of coronary artery disease, congestive heart failure and hypertension. The physician assessment indicated that based on a detailed exam and workup the findings were most consistent with bilateral pulmonary consolidations as well as pleural effusions consistent with early onset pneumonia.
    A nurse's noted dated 10/22/18 at 3:09 AM indicated that the patient was increasingly anxious by demonstrating periods of throwing his/her arms screaming and talking in a foreign language. The note indicated that Zyprexa 2.5 mg IM was administered at 3:18 AM for psychotic behavior.
    Interview with MD #2 on 5/21/19 at 1:30 PM indicated that he order Zyprexa 2.5 mg IM for the patient because he felt that the patient was actively delirious/psychotic. The record failed to reflect an assessment of the patient subsequent to the change in mental status by MD #2.
    MD #2 indicated that he was not concerned administering the Ativan followed by the Zyprexa since the patient's respiratory status had been stable all night. Review of the clinical record indicated that at 4:10 AM blood gases were obtained and at 4:12 AM CPR was initiated.
    Interview with the Head of the Hospitalist Program (MD #3) on 5/2/19 at 10:15 AM

indicated that he reviewed the case and felt that physician documentation was lacking. MD #3 indicated that the facility has a delirium protocol and includes the option of administering anti-psychotic medication, however he would have weighed the risks prior to administration.

Review of the Delirium protocol indicated that for non ICU patients with a positive Confusion Assessment Method (CAM) unrelated to alcohol, there are guidelines for care inclusive of suggested medications. Review of the clinical record failed to reflect that MD #2 completed a CAM assessment and/or a rationale for the use of Zyprexa in a patient over 65 years old.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) (3) and/or (d) Medical Records (3), and/or (e) Nursing Service (1) and/or (i) General (6),

5. *Based on clinical record review, policy review and interview for 1 of 3 patients evaluated in the ED (Patient #2) the facility failed to ensure that comprehensive assessments were completed. The findings include the following:
    a. Patient #2 presented to the emergency department on 10/21/18 at 4:57 PM with shortness of breath. The patient had a past medical history of coronary artery disease, congestive heart failure and hypertension. The physician assessment indicated that based on a detailed exam and workup the findings were most consistent with bilateral pulmonary consolidations as well as pleural effusions consistent with early onset pneumonia.
        i. Review of the clinical record indicated that in triage on 10/21/18 at 4:58 PM vital signs were obtained inclusive of a temperature that was 96.9 F. Review of the clinical record indicated that although the patient's vital signs were obtained every 1-2 hours the patient's temperature was not included in those vital signs and was assessed again until 10/22/18 at 11:00 AM that identified a temperature of 94.9 F.
        ii. The physician assessment for Patient #2 completed on 10/21/18 at 7:48 PM indicated that the patient was alert and appropriate. The clinical record indicated that on 10/22/18 at 1:50 AM Ativan 0.5mg intravenously was administered. The record failed to identify the rationale for the administration of the medication and/or the patient's response to the medication. Interview with RN #1 on 5/2/19 at 2:30 PM indicated that the patient was getting confused and swinging his/her legs over the rail. The record failed to reflect an assessment of the patient secondary to the change in mental status and/or a reassessment of the patient to determine the efficacy of the interventions.
        iii. Review of Patient #2's nurse's noted dated 10/22/18 at 3:09 AM indicated that the patient was increasingly anxious by demonstrating periods of throwing his/her arms, screaming and talking in a foreign language. The note indicated that Zyprexa 2.5 mg IM was administered at 3:18 AM for "psychotic behavior". The record failed to reflect a reassessment of the patient after the administration of the medication to determine the efficacy of the intervention. Interview with MD #2 on 5/21/19 at 1:30 PM indicated that he order Zyprexa 2.5 mg IM for the patient because he felt that the patient was actively delirious/psychotic.

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iv. The Nursing notes after the administration of the Zyprexa dated 10/22/18 indicated that antibiotics were administered at 3:46 AM, the next documentation at 4:10 AM indicated that blood gases were obtained and at 4:12 AM indicated that a "pulse check" was completed and CPR was initiated.

v. Interview with RN #2 on 5/2/19 at 8:30 AM indicated that the code button was pressed immediately and CPR was initiated. RN #2 stated that the patient was unresponsive and compressions were started. The record indicated that CPR was continued and at 4:23 AM the patient had a pulse of 127 and a BP of 105/55.

Review of the clinical record with the Director of Quality on 5/1/19 at 2:00 PM failed to reflect accurate documentation of the cardiac arrest. The record failed to reflect documentation of the events prior to the event.

Review of the Resuscitative Process Policy indicated that the RN assigned to the patient must document events leading up to the event and the outcome of the resuscitation.

Review of the Assessment and Reassessment policy indicated each patient will have ongoing assessments by the RN as warranted by the dynamic status of the patient response. The RN will communicate any abnormal findings to the patients care team throughout the ED stay.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3), and/or (e) Nursing Service (1) and/or (i) General (6),

6. *Based on clinical record review, interview and policy review for 1 of 3 patients evaluated in the Emergency Department (Patient #2) the facility failed to ensure that the clinical record reflected that a critical laboratory value was communicated to the physician and/or that a comprehensive clinical record was maintained. The findings include the following:

   a. Patient #2 presented to the emergency department on 10/21/18 at 4:57 PM with shortness of breath. The patient had a past medical history of coronary artery disease, congestive heart failure and hypertension. The physician assessment indicated that based on a detailed exam and workup the findings were most consistent with bilateral pulmonary consolidations as well as pleural effusions consistent with early onset pneumonia.

      i. Review of Patient #2's clinical record dated 10/21/18 at 8:04 PM indicated that the patient had a Lactic acid level of 2.4 mmol/L (normal 0.5-1.9). The record indicated that this was a critical result that was called to RN #1. In this same timeframe, the patient was also experiencing tachycardia. Review of the record with the ED Nurse Manager on 5/2/19 at 8:50 AM indicated that the lactic acid level was reported at 8:04 PM to RN #1 and the record should reflect a note related to physician notification.

      Interview with RN #1 on 5/1/19 at 2:30 PM indicated that he did not recall reporting of the Lactic acid level to the physician. The record failed to reflect documentation that the critical laboratory value had been reported by RN #1 to a physician. However, MD #1 ordered a redraw at 8:31 PM and MD #2 ordered a lactic acid level at 9:39 which resulted at 10:51 PM as 2.0 mmol. MD #2 stated on 5/21/19 at 1:30 PM that saw the elevated Lactic acid level in the computer and would evaluate the whole patient prior to

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treatment.

ii. Review of clinical record indicated that the patient had received Zofran 4 mg injection at 3:30 AM. The record failed to reflect the reason for the medication and/or a reassessment of the patient to determine the efficacy.